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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,115	12/14/2001	Charles L. Sawyers	30435.53USD2	4057

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EXAMINER

HAMA, JOANNE

ART UNIT PAPER NUMBER

1632

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/022,115	<b>Applicant(s)</b> SAWYERS ET AL.	
	<b>Examiner</b> Joanne Hama, Ph.D.	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 21-26 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-26 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

The final rejection of March 25, 2005 has been withdrawn. The Examiner has reopened the case and has reexamined the claims.

Claims 21-26 and 35 are pending.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-23 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Crowley et al., (1993, PNAS, USA, 90: 5021-5025).

Crowley et al. teach that human PC3 prostate carcinoma cells were inoculated subcutaneously into nude mice. These cells were transfected with a reporter construct comprising a CAT reporter. Eight weeks after subcutaneous inoculation of these cells into nude mice, CAT activity was used to detect the cells in regional lymph nodes, femurs, lungs, and brain, and thus mimicked the organ tropism observed for naturally occurring metastases of prostate cancer (Crowley et al., page 5022, 2<sup>nd</sup> col. 1<sup>st</sup> parag. under Results, see also Table 1). Crowley et al. also teach that PC3 cells were

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transfected with the CAT reporter construct and a construct comprising a nucleic acid sequence encoding a mutant u-PA (Ser<sup>356</sup> to Ala) which lacks enzymatic activity but which retains full receptor binding affinity. While tumor growth in the cells comprising mutant uPA construct was similar to that of cells not comprising the construct, Crowley et al. teach that mice injected with cells comprising the mutant uPA construct exhibited background levels of lymph node CAT activity, indicating that these clones were unable to establish metastatic tumor foci within the regional lymph nodes. In addition to this, the levels of CAT activity in cells comprising mutant uPA were 40 to 100 fold lower in the brain and 10 to 20 fold lower in lungs (Crowley et al., page 5023, 2<sup>nd</sup> col., 2<sup>nd</sup> parag.).

Therefore, Crowley anticipates claims 21-23 and 26.

Claims 21, 22, 24, and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Monosov et al. (U.S. Patent 5,491,284, patented, February 13, 1996; filed December 17, 1993).

Monosov et al. teach how to make a mouse model for cancer. Monosov et al. teach that the embodiments that are used to make the mouse model encompass that the human neoplastic tissue is intact and is transplanted onto the corresponding organ of the non-human mammalian model, wherein the model is sufficiently immunodeficient to allow the transplanted tissue to grow and mimic the progression of neoplastic disease in the human donor (Monosov et al., col. 3, 1<sup>st</sup> parag.). Monosov et al. teach that implantation of tissue from a human prostatic carcinoma into the prostate of a recipient

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animal is carried out by surgically forming an opening in the prostate and then placing 5 tissue specimens of approximately 0.1x0.1x0.1 cm in size under the prostate capsule. After placement of the tissue specimen, the opening in the capsule is closed with appropriate sutures (Monosov, et al., col. 5, 3<sup>rd</sup> parag.). Monosov et al. teach that the animal model can be used to screen new anti-neoplastic agents to determine the ability of such agents to affect tumors at the primary site and also at distant metastatic sites or to prevent distant metastases from occurring. The models are also useful for individualized chemosensitivity testing of a cancer patient's tumors (Monosov, et al., col. 7, 4<sup>th</sup> parag.)

Therefore, Monosov et al. anticipate claims 21, 22, 24, and 26.

Claims 21, 22, 26, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stearns and Wang (1992, Cancer Research 52: 3778-3781).

Stearns and Wang teach that PC-3 ML human prostatic tumor cells were injected i.v. into the tail vein of SCID mice (Stearns and Wang, page 3779, 2<sup>nd</sup> col., parag. under "Effect of Taxol on tumor Growth *in Vivo*"). On the 6<sup>th</sup> day following tumor inoculation, the mice were injected i.v. via the tail vein with taxol (50 mg/m<sup>2</sup>/day and 250 mg/m<sup>2</sup>/day in 0.2 ml). Ten mice were treated with each taxol dosage tested and five control mice received equivalent amounts of polyoxyethylated castor oil, the vehicle in which taxol was formulated. 15 days after treatment, the mice were sacrificed and examined for tumors by dissection and histology. Gross dissection revealed that tumors grew specifically in the lumbar vertebrae (i.e. filling the bone marrow) in all the control mice. Gross dissection of the taxol treated mice showed that none of the 20 mice exhibited

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noticeable tumors in any tissues examined (lungs, liver, colon, testicles, muscle, brain, vertebrae). 20 days after treatment, there was tumortissue, but only in the bone marrow of the lumbar vertebrae of the taxol treated mice. The tumor burden in mice exposed to 50 mg/m<sup>2</sup>/day or 250 mg/m<sup>2</sup>/day taxol was minimal and about the same as that observed in untreated mice sacrificed at day 5 (Stearns and Wang, page 377, 2<sup>nd</sup> col., parag. under "Effect of Taxol on tumor Growth *in Vivo*" to page 3780, 1<sup>st</sup> col., 1<sup>st</sup> parag.).

Therefore, Stearns and Wang teach claims 21, 22, 26, and 35.

Examiner's note: Claim 25, wherein the xenograft is within a bone marrow cavity of the mouse, appears to be free of the art.

Claim 25 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 25 depends on claim 21, which is anticipated in the art.

### **Conclusion**

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

